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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,687	11/02/2005	Garry A. Palmateer	CRA-0001	3729
59115	7590	09/24/2007		
BRUNET & CO. LTD. 10712 MELROSE DR. KOMOKA, ON N0L-1R0 CANADA			EXAMINER WOOD, AMANDA P	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,687	PALMATEER ET AL.	
	Examiner	Art Unit	
	Amanda P. Wood	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-11,13-16,19-22,25,27,29 and 86 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,13-16,19-22,25,27,29 and 86 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2005</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 are presented for consideration on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites the phrase "enhancing agent" in step f) of claims 1, 29, and 86, as well as in line 2 of claim 11. It is unclear what Applicant means by "enhancing agent" (i.e., what does this agent do, what does it enhance?). Applicant gives the broad example of "quaternary ammonium homopolymer" for an enhancing agent, but is this the only thing that would work as an enhancing agent? Applicant does not provide a specific definition in the disclosure of "enhancing agent", therefore, for purposes of examination, the Examiner will assume that by "enhancing agent," Applicant means an agent, or accelerator, that causes chemical excitation of a molecule so that it emits light in the form of chemiluminescence.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps related to how the quantity of enzyme, and therefore, the quantity of bacteria in a sample, corresponds to a measured light emission (i.e., Applicant needs to provide steps which show construction of a calibration curve).

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 86 is unclear because the preamble claims a kit, but the claim comprises only method steps, therefore, the claim has been treated on the merits as a method claim.

Claim 29 recites the limitation "the quantity of said enzyme" in line 2 of step g). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelis (US 5,861,270).

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A method is claimed for determining the presence and/or quantity of coliform bacteria in a water sample.

Nelis beneficially teaches a two-stage enzymatic method for the detection of coliform bacteria wherein bacteria are concentrated on a membrane filter. Nelis teaches that bacteria are separated from a water sample by concentrating the bacteria on a membrane filter and placing the filter and bacteria concentrated thereon on a growth medium, which can comprise a liquid growth medium (i.e., a broth) so as to support growth of the bacteria, and adding an inducer for inducing a marker enzyme (i.e., either β -D-galactosidase or β -D-glucuronidase) during growth and metabolism, wherein the inducer can comprise IPTG or methyl- β -D-glucuronide, and inhibitors of competing bacteria (see, for example, Abstract, col. 5, lines 1-20). Nelis beneficially teaches that after incubating the filter containing the bacteria in growth medium, the filter is removed from the growth medium and placed on an adsorbent cellulose pad impregnated with a medium to assay the marker enzyme. Nelis teaches that the medium used to assay the marker enzyme can be a chemiluminogenic substrate such as AMPGD (3-(4-methoxyspiro[(1,2-dioxetane-3,2'-tricyclo[3.3.1.^{3,7}]decan]-4-yl)phenyl)- β -D-galactopyranoside), or derivatives thereof, and (3-(4-methoxyspiro[(1,2-dioxetane-3,2'-(5'-chloro)-tricyclo[3.3.1.^{3,7}]decan]-4-yl)phenyl)- β -D-glucuronide), or derivatives thereof. In addition, Nelis teaches that the assay medium contains a membrane permeabilizer, preferably polymyxin B sulfate, colistin methanesulfonate, or a mixture of these with lysozyme. Furthermore, Nelis teaches that the membrane filter is sprayed with an accelerator to cause the colonies on the filter to become

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chemiluminescent, wherein the accelerator (i.e., enhancer) comprises a cationic polymer and an alkalinizing agent (see, for example col. 6, lines 1-60). Nelis further teaches that a luminometer may be used to measure overall light emission in detecting bacteria by chemiluminescence reactions (see, for example, col.3, lines 1-8). In addition, Nelis teaches that these methods may be used to either detect the presence of coliform bacteria, or to determine the quantity of coliform bacteria, in a sample. In particular, Nelis teaches that enumeration of bacteria on the membrane filter is based on the chemiluminometric measurement of β -glucuronidase activity (see, for example, col. 7, lines 20-55).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Nelis, based upon the beneficial teachings provided by Nelis and with respect to the knowledge and teachings available to one of ordinary skill in the art. In particular, it would have been obvious to one of ordinary skill in the art at the claimed invention was made to provide a second filter means for separating the bacteria from the liquid culture, so as to concentrate the bacteria grown during the culturing and incubation step onto a filter for the enzymatic assay steps. One of skill in the art would have had the knowledge, skill, and motivation to provide this second filter means not expressly taught by Nelis because a second filtering step would concentrate bacteria from the first filter and liquid medium, and allow for better detection of bacteria from the sample. The result-effective adjustment of particular conventional working conditions (e.g., using a particular enhancing agent, and/or measuring luminescence in a particular manner) is deemed merely a matter of

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judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

APW


RALPH GITOMER
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GROUP 1200